## REMARKS

In view of the preceding amendments and the comments which follow, and pursuant to 37 CFR §1.111, amendment and reconsideration of the Official Action of November 4, 2004 is respectfully requested by Applicants.

A "Claims Listing" dated 3/17/05 is submitted herewith.

A copy of Applicants' express abandonment of U.S. Serial No. 10/087,612, which was filed on March 14, 2005, is attached hereto.

Claims 4, 8, 9, 12, 15, 34, 35, 37, and 38 have been cancelled. Claims 1, 22, 29, 33 and 36 have been amended. Support for the recitation "a label which is detectable upon binding of the antibody to the analyte" added to claims 33 and 38 is found in the originally filed specification in paragraphs 28 and 79. No new matter has been added.

Claims 1-3, 5-7, 10, 11, 13, 14, 16-33, and 36 remain pending for examination.

Rejection under 35 USC §112, second paragraph

Claims 9, 12, 15, 33, and 36 have been rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The examiner argues that claims 33 and 36 are indefinite in not reciting the type/structure of the analyte to be detected. Additionally, the claims are indefinite and incomplete for failing to define how the "complex formed by the antibody and the analyte" is to be detected.

Applicants have amended claims 33 and 36 to recite "an ecstasy drug or an ecstasy drug derivative analyte". These claims have also been amended to recite "a label which is detectable upon binding of the antibody to the analyte".

Claims 12 and 15 have been rejected for use of the term "in a manner equivalent to".

Applicants have cancelled claims 12 and 15, thereby rendering this basis for rejection moot.

Claim 9 has been rejected for its definition of Q being in conflict with the definition of Q in claim 7, from which claim 9 depends.

Applicants have cancelled claim 9, thereby rendering this basis for rejection moot.

The examiner's reconsideration of the rejections under 35 USC §112, second paragraph, is respectfully requested.

Double patenting rejections

Claims 1-9, 16, and 22-38 have been rejected for being in conflict with claims 1-45 of application no. 10/087,612. Further, claims 1-6, 29, and 30 have been provisionally rejected as claiming the same invention as that of claims 1-4, 7, 31, and 36 of copending application no. 10/087,612.

A Notice of Express Abandonment of application no. 10/087,612 was filed by Applicants on March 14, 2005, a copy of which has been appended hereto. Thus these rejections for double patenting are avoided.

Claims 11, 12, 14-28, and 33-38 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17, 18, 31, and 42-44 of copending application no. 10/087,469.

Applicants inform the examiner that in the event any pending claims are still in conflict at the time of patenting of either claims 11, 14, 16-28, 33, and/or 36 in the instant application or claims 17, 18, 31, and/or 42 in copending application no. 10/087,469, a terminal disclaimer will be filed by Applicans as appropriate.

Claims 11, 12, and 14-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8 and 9 of copending application no. 10/622,524.

Applicants inform the examiner that claims 8 and 9 of application no. 10/622,254 have been cancelled from that application. They are now pending in an application filed on March 9, 2005 that is a divisional of serial no. 10/622,254. In the event any pending claims are still in conflict at the time of patenting of either instant claims 11, 14, and/or 16-21 in the instant application or claims 8 and 9 in the before-mentioned divisional application, a terminal disclaimer will be filed by Applicant as appropriate.

Rejection under 35 USC §102 (b)

Claims 1-4, 6, 11, 12, 14-25, 26-28, 29, 32, and 33-38 have been rejected under 35 USC §102 (b) as being anticipated by each of Gross (US 3,996,344, hereinafter "Gross"), Soares (US 4,016,146, hereinafter "Soares"), Buechler et al (US 5, 470,997, hereinafter "Buechler"), Huber et al (US 5,976,812, hereinafter "Huber"), Heiman et al (US 5,262,333, hereinafter "Heiman"), Hu et al (US 5,135,863, hereinafter "Hu"), Byrnes et al. (US 4,868,132, hereinafter "Byrnes"), or Schneider et al (US 3,878,187, hereinafter "Schneider"). The Examiner argues that each of the references describes methamphetamine derivatives in which the phenyl ring is substituted at the *para* position with an activated linker moiety. The linker moiety can be reacted with an immunogenic carrier or label to form the corresponding para-substituted methamphetamine immunogen or detectably labeled methamphetamine derivative. The para-substituted activated haptens, immunogens, tracers, and antibodies of the references anticipate the para-substituted activated haptens, immunogens, tracers, and antibodies of the instant claims. Given the structural similarities of the haptens of the instant invention and those of the prior art, the antibodies of the prior art would be expected to inherently have the same specificity for MDEA as the antibodies of the instant claims.

Applicants respectfully disagree with the examiner with regard to each of the cited references. Applicants agree that the cited references disclose a *para*-substituted phenyl ring; however, with the exception of Huber, none of the references disclose N-ethyl substituted derivatives. And none of the references teach the advantages of using N-ethyl amphetamine conjugates to obtain antibodies that specifically and preferentially bind MDEA.

The examiner argues that the antibodies of the prior art would be expected to inherently have the same specificity for MDEA as the antibodies of the instant claims. However, Applicants draw the examiner's attention to the antibody characteristics taught by Heiman in Table 2, columns 21 and 22. Although Heiman's antibody will detect MDEA, the antibody is neither specific nor preferential for MDEA, nor would it be suitable for use in an assay to determine MDEA in a sample. Thus, it cannot be logically assumed that any antibody produced in response to an immunogen derived at the *para* position of amphetamine will have the same specificity for MDEA as the antibodies of the present invention.

Specifically with regard to Gross, the structures taught by Gross are phenethylamine derivatives. See column 3, structures (1)-(4), and column 6, structure (5). These structures all lack the N-ethyl substitution of the haptens, tracers, and immunogens of present invention and therefore cannot anticipate the compounds present invention. Furthermore, the structures taught by Gross do not make the compounds of present invention obvious because Gross contains no teaching that would lead to the N-ethyl-substituted derivatives of the present invention, nor does Gross teach the benefit of using N-ethyl amphetamine derivatives to obtain antibodies specific for MDEA as taught by the present invention. It follows, therefore, that the antibodies, kits, and methods of the present invention are likewise neither anticipated nor made obvious by the disclosure of Gross.

Specifically with regard to Soares, the structures taught by Soares are phenethylamine derivatives. See column 3, structures (1)-(4), and column 6, structure (5). These structures all lack the N-ethyl substitution of the haptens, tracers, and immunogens of present invention and therefore cannot anticipate the compounds present invention. Furthermore, the structures taught by Soares do not make the compounds of present invention obvious because Soares contains no teaching that would lead to the N-ethyl-substituted derivatives of the present invention, nor does Soares teach the benefit of using N-ethyl amphetamine derivatives to obtain antibodies specific for MDEA as taught by the present invention. It follows, therefore, that the antibodies, kits, and methods of the present invention are likewise neither anticipated nor made obvious by the disclosure of Soares.

Specifically with regard to Buechler, the structures taught by Buechler are amphetamine derivatives. See Figure 1, Example 15. These structures all lack the N-ethyl substitution of the haptens, tracers, and immunogens of present invention and therefore cannot anticipate the compounds present invention. Furthermore, the structures taught by Buechler do not make the compounds of present invention obvious because Buechler contains no teaching that would lead to the N-ethyl-substituted derivatives of the present invention, nor does Buechler teach the benefit of using N-ethyl amphetamine derivatives to obtain antibodies specific for MDEA as taught by the present invention. It follows, therefore, that the antibodies, kits, and methods of the present invention are likewise neither anticipated nor made obvious by the disclosure of Buechler.

Specifically with regard to Huber, the structures taught by Huber are amphetamine derivatives. See the structure at column 2, line 40, and Figure 2, structures 15-17. These structures are all maleimide derivatives, however, and therefore cannot anticipate the compounds present invention. Furthermore, the structures taught by Huber do not make the compounds of present invention obvious because Huber contains no teaching that would lead to the derivatives of the present invention, nor does Huber teach the benefit of using N-ethyl amphetamine derivatives to obtain antibodies specific for MDEA as taught

by the present invention. It follows, therefore, that the antibodies, kits, and methods of the present invention are likewise neither anticipated nor made obvious by the disclosure of Huber.

Specifically with regard to Heiman, the structures taught by Heiman are amphetamine derivatives. See structures 7, 8, 12, and 13. These structures all lack the N-ethyl substitution of the haptens, tracers, and immunogens of present invention and therefore cannot anticipate the compounds present invention. Furthermore, the structures taught by Heiman do not make the compounds of present invention obvious because Heiman contains no teaching that would lead to the N-ethyl-substituted derivatives of the present invention, nor does Heiman teach the benefit of using N-ethyl amphetamine derivatives to obtain antibodies specific for MDEA as taught by the present invention. It follows, therefore, that the antibodies, kits, and methods of the present invention are likewise neither anticipated nor made obvious by the disclosure of Heiman.

Specifically with regard to Hu, the structures taught by Hu are amphetamine derivatives. See the structure at column 4, line 25, and in claim 1. These structures lack the N-ethyl substitution of the haptens, tracers, and immunogens of present invention and therefore cannot anticipate the compounds present invention. Furthermore, the structures taught by Hu do not make the compounds of present invention obvious because Hu contains no teaching that would lead to the N-ethyl-substituted derivatives of the present invention, nor does Hu teach the benefit of using N-ethyl amphetamine derivatives to obtain antibodies specific for MDEA as taught by the present invention. It follows, therefore, that the antibodies, kits, and methods of the present invention are likewise neither anticipated nor made obvious by the disclosure of Hu.

Specifically with regard to Byrnes, the structures taught by Byrnes are amphetamine derivatives. See the structures in Figs. 2B, 7, 9A, and 9D. These structures all lack the N-ethyl substitution of the haptens, tracers, and immunogens of present invention and therefore cannot anticipate the compounds present invention. Furthermore,

the structures taught by Byrnes do not make the compounds of present invention obvious because Byrnes contains no teaching that would lead to the N-ethyl-substituted derivatives of the present invention, nor does Byrnes teach the benefit of using N-ethyl amphetamine derivatives to obtain antibodies specific for MDEA as taught by the present invention. It follows, therefore, that the antibodies, kits, and methods of the present invention are likewise neither anticipated nor made obvious by the disclosure of Byrnes.

Specifically with regard to Schneider, the structures taught by Schneider are amphetamine derivatives. See column 2, line 50. These structures all lack the N-ethyl substitution of the haptens, tracers, and immunogens of present invention and therefore cannot anticipate the compounds present invention. Furthermore, the structures taught by Schneider do not make the compounds of present invention obvious because Schneider contains no teaching that would lead to the N-ethyl-substituted derivatives of the present invention, nor does Schneider teach the benefit of using N-ethyl amphetamine derivatives to obtain antibodies specific for MDEA as taught by the present invention. It follows, therefore, that the antibodies, kits, and methods of the present invention are likewise neither anticipated nor made obvious by the disclosure of Schneider.

The examiners reconsideration of the rejection under 35 USC §102 (b) is respectfully requested by Applicants.

Claims 5, 7-9, 30, and 31 have been rejected under 35 USC §102 (b) as being anticipated by Huber. The examiner argues that Huber describes *para*-derivatized amphetamine haptens wherein the linker contains both an alkylene moiety directly attached to the benzene ring and a carbonyl group. These activated haptens are useful in preparing the corresponding amphetamine immunogens, antibodies, and tracers and anticipate the corresponding immunogens, tracers, antibodies and their method of use in an immunoassay of instant claims 5-7 wherein L is alkylene and X is –CO–. Claims 7-9 and 31 contain the added limitation that $R_1$ is ethyl and $R_2$ is methyl, i.e., the terminal amine group is –N(Et)Me. Huber specifically describes this compound limitation at

column 2, lines 32-47 wherein $R_4$ and $R_5$ can be $-CH_3$ (methyl) or $-C_2H_5$ (ethyl), i.e., the terminal amine group is –N(Et)Me. Therefore Huber anticipates the instant claims.

Applicants respond that claims 5 and 7 depend from independent claim 1, and claims 30 and 31 depend from independent claim 29. Claims 8 and 9 have been cancelled. The patentability of claims 1 and 29 has been argued above, and claims 5, 7, 30, and 31 should enjoy the same patentability as the claims from which they depend.

The examiners reconsideration of the rejection of claims 5, 7-9, 30, and 31 under 35 USC §102 (b) is respectfully requested by Applicants.

Applicants submit that their application is now in condition for allowance, and favorable reconsideration of their application in light of the above amendments and remarks is respectfully requested. Allowance of claims 1-3, 5-7, 10, 11, 13, 14, 16-33, and 36 at an early date is earnestly solicited.

The Examiner is hereby authorized to charge any fees associated with this Amendment to Deposit Account No. 02-2958. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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